Docket No.: 2294-0122PUS1

(PATENT)

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Alfonso ROMERO et al.

Application No.: 10/594,004 Confirmation No.: 8959

Filed: September 25, 2006 Art Unit: 1616

For: PROLONGED-RELEASE COMPOSITIONS

COMPRISING TORASEMIDE AND A

MATRIX-FORMING POLYMER

Examiner: A. L. Fisher

## DECLARATION SUBMITTED UNDER 37 C.F.R. § 1.132

Honorable Commissioner
Of Patents and Trademarks
P.O. Box 1450
Alexandria, VA 22313-1450

September 3, 2010

Sir:

I, Dr. Antonio Guglietta of the Pharmaceutical Research and Development Center, Ferrer Internacional, S.A., Spain, do hereby declare the following:

I have attached a copy of my curriculum vitae to this Declaration.

I am the Research and Development Director and have worked in this field for over ten years.

I am familiar with the above referenced patent application and the area of science dealing with prolonged release compositions.

I have read and understand the subject matter of the Office Action of March 17, 2010.

The following comments are offered in support of the patentability of the instant invention.

The Examiner seems to believe that a skilled artisan would find the invention of Application No. 10/594,004 obvious because of the following references: Maegerlein et al., Azarmi et al., Pankhania et al., Berner et al. and Kaplan. I disagree.

In particular, lactose is a well known diluent which is normally used in immediate release formulation, not in controlled release formulations since it normally does not influence or control the release profile. On the contrary, it is sometimes used as a release enhancer. Scientists working in the controlled-release area would not have reasonably expected success in obtaining a controlled release formulation by using lactose.

To assist the Examiner in appreciating the instant invention, Applicants make the following points. The present invention has a formulation containing torasemide, a matrix forming polymer and lactose as the main diluent. This results in a prolonged-release formulation of toraseimide which shows a kinetic profile with fewer fluctuations and steadier levels. The percentage of lactose in the preferred formulations of the invention is about 50% of the blend (see examples 6-9). On the other hand, the matrix forming polymer is present in a small proportion in the formulation of the invention; normally less than 20% of the total composition, and more preferably from 2-5%.

To illustrate the kinetic profiles of examples of the torasemide formulations (tablets) of the claimed invention, Meyprogat<sup>®</sup> 90 (i.e. guar gum) at 10, 5 and 3% of the total tablet weight was tested as shown in the Table below for the 5 mg tablet dose (5 mg torasemide).

| Formulation               | T1604  | T1704  | T1804  |
|---------------------------|--------|--------|--------|
| Torasemide                | 5.9 %  | 5.9 %  | 5.9 %  |
| Corn starch               | 36.2 % | 36.2 % | 36.2 % |
| Colloidal Silicon Dioxide | 0.5 %  | 0.5 %  | 0.5 %  |
| Meyprogat® 90             | 10.0%  | 5.0 %  | 3.0 %  |
| Magnesium stearate        | 0.3 %  | 0.3 %  | 0.3 %  |
| Lactose                   | 47.1%  | 52.1 % | 54.1 % |

The following dissolution tests were performed with hydrochloric acid 0.1 N.

In comparison with Sutril® (Immediate release formulation), the experimental tablets showed a prolonged release behaviour starting from 3% of guar gum (batch T1804). The total

release of the active in this batch (T1804) was produced in 5 hours. Batches with 5% and 10% of the excipient (i.e. T1704 and T1604) presented a 75% active release within 5 hours with a similar kinetic profile. The following table and figure show the results of the kinetic profile of these formulations.

|               | Sutril 5 mg                 |         | Batch T1604                          |              | Batch T1704                          |              | Batch T1804                     |              |
|---------------|-----------------------------|---------|--------------------------------------|--------------|--------------------------------------|--------------|---------------------------------|--------------|
| Time<br>(min) | Release per time fraction % | Release | Release<br>per time<br>fraction<br>% | Release<br>% | Release<br>per time<br>fraction<br>% | Reiease<br>% | Release<br>per time<br>fraction | Reiease<br>% |
| 0             | 343                         | 0       |                                      | 0            | œ                                    | 0            |                                 | 0            |
| 0.5           | 98.2                        | 98.2    | 22.5                                 | 22.5         | 23.4                                 | 23.4         | 26.6                            | 26.6         |
| 4             | 2.3                         | 100.5   | 10.2                                 | 32.7         | 7.2                                  | 30.6         | 7.4                             | 34.1         |
| 2             | 0.4                         | 101.3   | 7.5                                  | 47.7         | 6.4                                  | 43.5         | 12.7                            | 59.6         |
| 3             | -0.6                        | 100.1   | 5.7                                  | 59.0         | 5.7                                  | 54.8         | 12.8                            | 85.1         |
| 4             | -0.3                        | 98.9    | 3.7                                  | 73.9         | 6.1                                  | 79.1         | 3.1                             | 97.5         |

Table. Release values (with HCl 0.1N) for tablets manufactured with Meyprogat® 90.

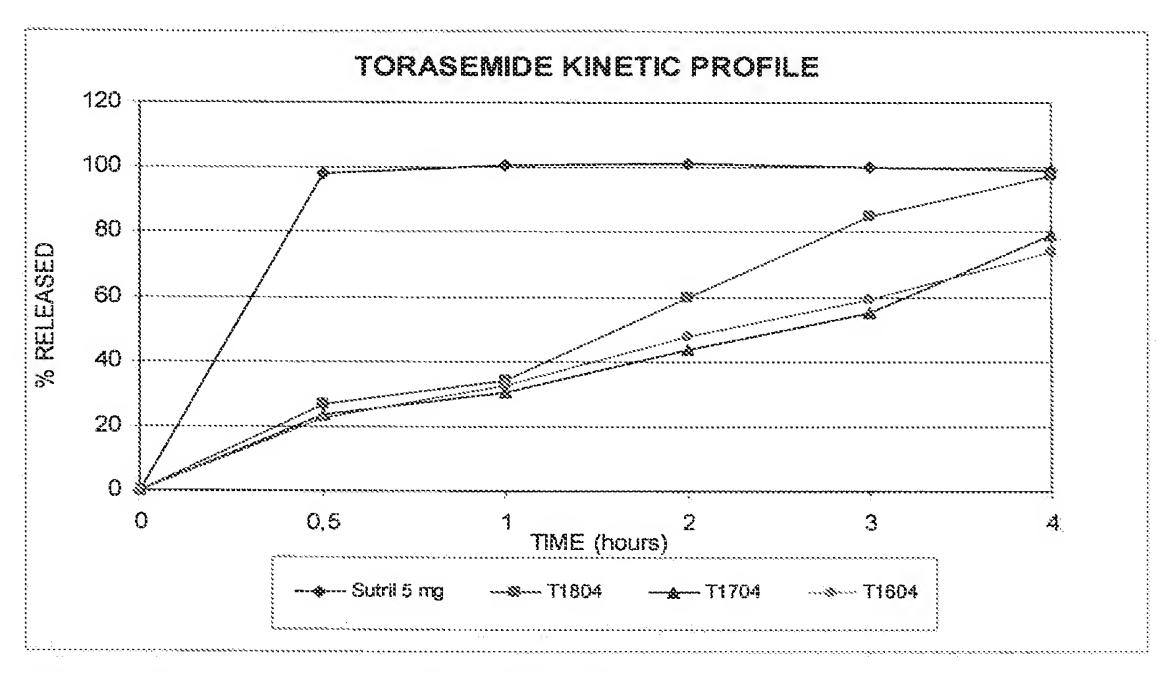


Figure. Release profiles (with HCl 0.1N) of Torasemide from Meyprogat® 90matrix tablets.

Appl. No. 10/594,004

The percentage of lactose in the experiments is above 45% with respect of the blend.

The amount of guar gum is less than 10% of the amount of lactose.

Therefore, it is my opinion that the invention as described in the current claims would not

have been obvious to a skilled artisan in view of the cited references. Neither do I believe that a

skilled artisan would have had a reasonable expectation of success if they had tried to combine

the cited references in order to obtain the instant invention.

The undersigned hereby declares that all statements made herein based upon

knowledge are true, and that all statements made based upon information and belief are believed

to be true; and further, that these statements were made with the knowledge that willful false

statements and the like so made are punishable by fine or imprisonment, or both, under Section

1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize

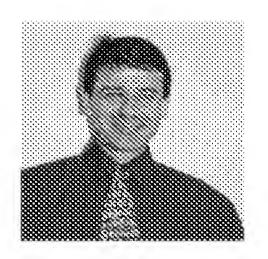
the validity of the application or any patent issued thereon.

DATED: September 3, 2010

Dr. Antonio Guglietta

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# Curriculum Vitae: Antonio Guglietta, MD, PhD (Updated Jul 2010)



#### **Personal**

Place of Birth Sperlonga (LT), Italy

Date of Birth March, 8 1956

**Citizenship** Italy

**Languages** Italian (fluent)

English (fluent)
Spanish (fluent)
Catalan (basic)
French (basic)

**Address** Grupo Ferrer Reserach Center

Juan de Sada 32 08028 Barcelona

Spain

Tel. ++ 34 (93) 509-3206 (business)

Fax ++ 34 (93) 411-2764

E-mail: <a href="mailto:guglietta-research@ferrergrupo.com">guglietta-research@ferrergrupo.com</a> (business)

E-mail: antonioguglietta@ureach.com (home)

**Education** 

1982: University "La Sapienza", Rome, Italy

M.D. degree (graduated with honors)

<u>Thesis:</u> Synthetic peptides related to the Dermorphins: Synthesis and biological activities of the shorter homologues

and of analogues of the heptapeptides

**1988:** University "La Sapienza", Rome, Italy

Ph.D. (Gastroenterology: graduated with honors)

Thesis: Central nervous regulation of gastric acid secretion.

Role of Bombesin, Dermorphin and Calcitonin

**1999** Management Development Program

University of Michigan, Business School

Ann Arbor, MI, USA

**2010:** University of Navarra IESE Business School:

Executive Development Programa (PDD)

#### **Residency and interships**

**1982** Resident

Hospital "Umberto I", Rome, Italy

(Surgery)

**1982** Resident

Hospital "Dono Svizzero", Formia, Italy

(Gynecology and Obstretics)

1982 Resident

Hospital "Umberto I", Rome, Italy

(Internal medicine)

**1983** Internship

Hospital "Nuovo Regina Margherita", Rome, Italy

(Gastroenterology)

**1983** Internship

Hospital "San Gallicano", Rome, Italy

(Dermatology & Venerology)

**Board Certification** 

1982 Italian Board Certification

Post graduate training

**1991** Gastrointestinal pharmacology

American Gastroenterological Association

New Orleans, LA, USA

**1993** Mucosal diseases of the gastrointestinal tract

American Gastroenterological Association

Boston, MA, USA

**1993** Gastrointestinal endoscopy

European Society of Gastrointestinal Endoscopy

Barcelona, Spain

1994 Clinical Immunology in gastroenterology and hepatology

American Gastrointestinal Association

New Orleans, LA, USA

**1995** Evolving Concepts in Gastrointestinal and Liver Diseases

American Gastrointestinal Association

San Diego, CA, USA

#### **Professional Organizations**

1986 -American Society for Neuroscience 1986 -International Brain Research Organization (IBRO) 1987 -American Association for the Advancement of Science 1987 -New York Academy of Science 1988 -American Endocrine Society 1988 -1991 North Carolina Society for Neuroscience American Gastroenterological Society 1991 -International Brain-Gut Society 1992 -International Union of Pharmacology - GI Section 1994-1995 -Gastroenterology Research Group Worldwide Hungarian Medical Academy **1996** -

#### **Scientific Offices held**

May 1996-July 1998

Member of the Communications Committee of International Union of Pharmacology (IUPHAR) - GI Section

July 1998-July 2002

Secretary of the International Union of Pharmacology (IUPHAR) - GI Section

Oct 1996-July 2000

Secretary of the International Brain-Gut Society

Founder and President of "International Researchers in Gastroenterology & Hepatology" a non-profit organization devoted to foster scientific interactions among investigators working in the area of gastroenterology and hepatology

around the world.

#### Manuscript and grants review activity

- Gastroenterology
- British J. Pharmacology
- Eur. Journal Pharmacology
- J. Pharm. Exp. Ther.
- Can. J. Physiol. Pharmacol.
- Life Sciences
- VA grant reviewer
- Am. J. Physiology

#### **Positions**

**1980-1982** Intern,

Institute of Medical Pharmacology, University "La Sapienza", Rome, Italy

**1982-1984** Post doctoral Fellow

Institute of Medical Pharmacology, University "La Sapienza", Rome, Italy

**1984-1987** Visiting Fellow,

Peptide Neurochemistry Group

National Institute of Environmental Health Sciences

Research Triangle Park, N.C., USA

**1987-1988** Visiting Associate

Peptide Neurochemistry Group

National Institute of Environmental Health Sciences

Research Triangle Park, N.C., USA

**1988-1990** Visiting Scientist

Clinical Biochemistry Dept. of Biochemistry

Glaxo Research Laboratories Research Triangle Park, NC, USA

1990-1991 Visiting Scientist

Immunopathology Dept. of Therapeutics

Parke-Davis Pharmaceutical Research Division of Warner-Lambert Company

Ann Arbor, MI, USA

**1991-1992** Research Associate

Immunopathology Dept. of Therapeutics

Parke-Davis Pharmaceutical Research Division of Warner-Lambert Company

Ann Arbor, MI, USA

1992- 2000 Senior Research Associate

Immunopathology Dept. of Therapeutics

Parke-Davis Pharmaceutical Research Division of Warner-Lambert Company

Ann Arbor, MI, USA

**2000- Date** R&D Director

Grupo Ferrer Internacional

Barcelona, Spain

#### **Awards**

Visiting Fellowship 1984-1987 the Fogarty International Center, National Institutes of Health, Bethesda, Maryland, U.S.A. Travel Grant provided by the 1986 Endocrine Society for the purpose of attending the 68<sup>th</sup> Annual Meeting of the Endocrine Society. Grant provided by the 1988 Organizing Committee of International Conference on Gastroenteric Biology for the purpose of attending such Conference Name included in: Who's Who in Science 1991-1997 and Engineering, 1st Ed. 1991, 2<sup>nd</sup> Ed. 1994-1995, 3<sup>rd</sup> Ed. 1996-1997. Marquis Who's Who. Name included in: Who's Who in America, 1992-1994 47th edition. 1992, 48th Edition 1994. Marquis Who's who. Name included in: Who's Who in the Midwest. 1994-1998 24th edition. 1994, 25<sup>th</sup> Ed. 1996, 26<sup>th</sup> Ed. 1998, Marquis Who's who 1994 International Men of the Year in recognition of his services to Research Published by International Biographical Centre, Cambridge, England Name included in: Who's Who in the world,12th 1995-1996 edition. Marquis Who's who 1995-1996. 1997-1998 Name included in Who's Who in Medicine and Health

care, 1st Ed. Marquis Who's Who. 1997-1998

#### **Selected invited lectures**

**Jun. 1989** 3rd International congress of Videoendoscopy

Abano Terme, Italy Title of the presentation:

Quantitative endoscopy: evaluation of ulcer

re-epithelization

**Jun. 1992** 3rd International symposium on experimental

ulcer disease: "Stress, Basic and Clinical Research;

Gastrointestinal Protection,

Zagreb, Croatia

Title of the presentation:

Possible clinical use of peptide growth factors in the

GI tract: perspectives and obstacles

**Nov. 1994** 5th International symposium on GI research:

Zagreb, Croatia.

Title of the presentation:

Preclinical evaluation of compounds with possible therapeutic activity in inflammatory bowel disease

May 1995 University of California San Diego

Cancer Center

San Diego, CA, USA Title of presentation:

Activity of EGF in the GI tract: Preclinical and clinical data

June 1996 IBC meeting on IBD

Philadelphia, PA USA Title of presentation:

Activity of EGF in animal models of IBD

**Apr 1997** University of Bologna, Italy

Institute of Hematology
Title of presentation:

"Can we protect the GI tract from chemiotherapics-induced

damage in hematologic patients ? Role of EGF"

**Apr. 1997** University of Padua, Italy

Institute of Internal Medicine

Title of presentation:

" New strategies for the pharmacotherapy of inflammatory

gastrointestinal diseases"

#### **Bibliography**

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   Guglietta, A., De Castiglione R., Faoro F., Perseo G.,
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   SYNTHETIC PEPTIDES RELATED TO DERMORPHIN. II. SYNTHESIS
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- 3. **Guglietta, A.**, Strunk C.L., Irons B.J., Lazarus L.H. CENTRAL NEUROMODULATION OF GASTRIC ACID SECRETION BY BOMBESIN-LIKE PEPTIDES. Peptides 6 (Suppl. 3):75-81, 1985.
- Lazarus L.H., Wilson W.E., Gaudino G., Irons B.J.,
   Guglietta, A.
   EVOLUTIONARY RELATIONSHIP BETWEEN NON MAMMILIAN AND MAMMILIAN PEPTIDES.
   Peptides 6 (Suppl. 3): 295-307, 1985.
- 5. Improta G., **Guglietta, A.**THE ROLE OF CAUDATE NUCLEUS IN DERMORPHIN-INDUCED CATALEPSY IN RATS.
  Peptides 6 (Suppl. 3): 161-164, 1985.
- 6. **Guglietta, A.**, Irons B.J., Lazarus L.H., Melchiorri P. STRUCTURE-ACTIVITY RELATIONSHIP OF DERMORPHIN ON GASTRIC SECRETION. Endocrinology 120 (5):2137-2147, 1987.
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8. Lazarus L.H., **Guglietta, A.**, Wilson W.E., Grimes L.M., Irons B.J. and Yajima H. NEUROMEDIN B: PHYSIOLOGICAL AND PHARMACOLOGICAL PERTUBATIONS.
Ann. New York Acad. Sci. 547: 404-414, 1988

Lazarus L.H., Irons B.J., Grimes L.M., Wilson W.E.,
 Guglietta, A., Yajima H.
 ASSESSMENT OF NEUROMEDIN B POLYCLONAL ANTIBODIES AS MOLECULAR PROBE IN NEURAL TISSUE.
 J. Neurol. Methods 23: 161-172, 1988

10. **Guglietta, A.**, Irons B.J., Lazarus L.H.
EFFECT OF BOMBESIN, DERMORPHIN AND SALMON CALCITONIN ON
GASTRIC ACID SECRETION IN RATS.
Meth. Find. Exp. Clin. Pharmacol. 10 (8):481-485, 1988

11. **Guglietta, A.**, Irons B.J., Lazarus L.H.
EFFECT AND MECHANISM OF ACTION OF LITHIUM CHLORIDE ON
GASTRIC ACID SECRETION.
Gastroenterology 95: 1454-1459, 1988

#### 12. Guglietta, A.

Regolazione Nervosa Della Secrezione Acida Gastrica: Ruolo Della Bombesina, Dermorfina e Calcitonina. Doctoral Thesis. Ph.D. program in Gastroenterology, University of Rome", La Sapienza ", Italy, July 1988.

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14. Lazarus, L.H., Wilson, W.E., de Castiglione, R.,

#### Guglietta, A.

DERMORPHIN GENE SEQUENCE PEPTIDE WITH HIGH AFFINITY AND SELECTIVITY FOR DELTA OPIOID RECEPTORS.

Journal Biological Chemistry 264 (6): 3047-3050, 1989.

15. **Guglietta, A.**, Irons, B.J., Lazarus, L.H., de Castiglione, R., Melchiorri, P. DIMERIC DERMORPHIN PEPTIDES: CENTRAL ADMINISTRATION SUPPRESSES GASTRIC ACID SECRETION THROUGH INTERACTION WITH MU-TYPE OPIOID RECEPTOR Meth. Findings Exp. Cli. Pharmacol. 11 (11): 663-670, 1989.

16. **Guglietta, A.**, Nardi, R.V. and Lazarus L.H. INDOMETHACIN (i.c.v.) REVERSES THE INHIBITORY ACTION OF PEPTIDES ON GASTRIC SECRETION. European J. Pharmacology 170 (1-2): 87-90, 1989.

17. Lazarus, L.H., Wilson, W.E., **Guglietta, A.** and de Castiglione R.

DERMORPHIN INTERACTION WITH RAT BRAIN OPIOID RECEPTORS: INVOLVEMENT OF HYDROPHOBIC SITES IN THE BINDING DOMAIN.

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- 19. **Guglietta, A.**, Hervada, T. and Nardi, R.V.
  THE USE OF A THYMIDINE INCORPORATION ASSAY IN THE
  EVALUATION OF THE HEALING PROCESS FOLLOWING ETHANOL OR
  INDOMETHACIN-INDUCED GASTRIC DAMAGE IN RATS.
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  COLONIC DAMAGE IN RATS.
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CLINICAL APPLICATIONS OF EPIDERMAL GROWTH FACTOR Eur. J. Gastroenterology and Hepatology 1995: 7: 945-950

26. M. Romano, CA Lesch, KS Meise, M. Veljaca, B. Sanchez, ER Kraus, R. Boland, A. Guglietta, RJ Coffey

INCREASED GASTRODUODENAL CONCENTRATION OF TRANSFORMING GROWTH FACTOR  $\alpha$  IN ADAPTATION TO ASPIRIN IN MONKEYS AND RATS.

Gastroenterology 110 (5): 1446-1455, 1996

27. Sizemore, N., Dudeck, RC., Barksdale, CM., Nordblom, GD., Mueller, WT., McConnel P., Wright, DS., **Guglietta, A**., Kuo, BS.

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Methods and Finding in Exp and Clin Pharmacol. 21 (2), 99-104, 1999

34. Song, Y. Connor DT., Doubleday R., Sorenson RJ, Sercel AD, Unangst PC, Tobias, B., Roth B., Gilbertsen RB, Chan K., Schrier DJ, Laemont K., Okonkwo GC., **Guglietta A**., Bornemeier DA., Dyer RD.

SYNTHESIS, STRUCTURE-ACTIVITY RELATIONSHIPS AND IN-VIVO EVALUATION OF SUBSTITUTED DI-T-BUTYLPHENOL AS A NOVEL CLASS OF POTENT SELECTIVE AND ORALLY ACTIVE PGHS-2 INHIBITORS, 1. THIAZOLONE AND OXAZOLONE SERIES.

J. Medicinal Chemistry 42 (7), 1151-1160, 1999

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- 36. CA. Lesch, ER Kraus, **A. Guglietta**3-ISOBUTYL GABA PROTECTS AGAINST EXPERIMENTALLY INDUCED DAMAGE IN THE UPPER GASTROINTESTINAL TRACT BY A CENTRALLY MEDIATED MECHANISM OF ACTION Journal of Digestive Protection 1 (2), 57-64, 2000
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  Drugs of the Future 26 (4), 335-341, 2001
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  J. Chemother. 13(5): 555-62, 2001
- 41. Lirussi, F. **A. Guglietta**IMPAIRED NATURAL KILLER CELL CYTOTOXIC ACTIVITY IN CHRONIC HEPATITIS C VIRAL INFECTION: A CONTROLLED STUDY
  Current Therapeutic Research
- 42. M. Guerrero, C. Albet, A. Palomer, **A. Guglietta**DRYING IN PHARMACEUTICAL AND BIOTECHNOLOGICAL INDUSTRIES
  Food Science and Technology International: Vol. 9 (3), 237-243, 2003

- 43. Improta G, Carpino F, Petrozza V, **Guglietta A**, Tabacco A, Broccardo M. CENTRAL EFFECTS OF SELECTIVE NK(1) AND NK(3) TACHYKININ RECEPTOR AGONISTS ON TWO MODELS OF EXPERIMENTALLY-INDUCED COLITIS IN RATS. Peptides: Vol. 24 (6), 903-911, 2003
- 44. Tarragó, C. Alemany, C., Palacin, C., Terencio, J., **Guglietta, A.** NOVES TECNOLOGIES EN LA RECERCA D'ANTIMICROBIANS Antimicrobians 55, 67-80, 2004
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#### Other:

Organizer and co-chairman of the symposium "New Approaches to Pharmacotherapy for Hepatic and Gastrointestinal Ulcerative and Inflammatory Disorders", Sperlonga (Italy), Sept. 3-7, 1996.

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